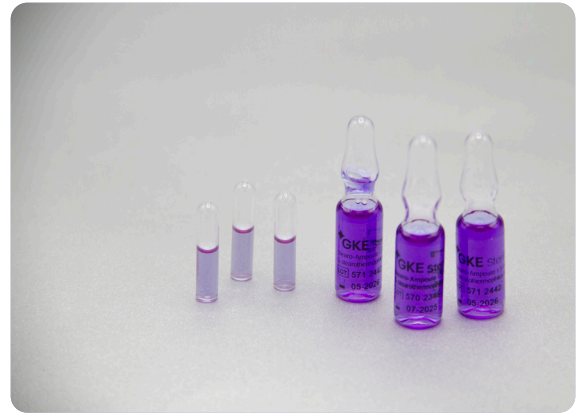


Stearo-Ampoules

FOR LIQUID AND WASTE STERILIZATION



Application

Stearo-ampoules are used for sterilization monitoring of liquids and solid sterile goods in liquids, e.g. eye lenses. They are suitable for all thermal processes, such as steam sterilization, liquid sterilization, sterilization with microwaves and their mixed forms, with the exception of dry heat.

They are particularly suitable for waste sterilization and can be used in 121°C and 134°C programs. When sterilizing waste in PP bags, approximately 1 liter of water should be added. The ampoule is immersed in the water. It is designed so that it does not float, but sinks. It is recommended that the ampoule be tied with a thread so that it can be easily removed. After sterilization, the ampoule is incubated. If all germs have been successfully inactivated, the color of the culture medium will not change. However, if not all germs have been inactivated, the remaining organisms will multiply by replication. This population growth becomes visible because the growth causes the pH value to change, causing a color change of the growth medium from purple to yellow/green.

Product Description

The glass ampoule contains a TSB nutrient solution with pH indicator.

- Two sizes available (1.5 ml | 0.2 ml)
- Two populations available (10^5 | 10^6 CFU/amp)

Ampoules are shipped in special cooled packaging, otherwise growth may occur during transportation.

Order Information

Art. No.	Quantity	Product Code	Dimension	Population	Application
225-550	50	B-S-AMP-10-5	11 x 44 mm	10^5 CFU	Standard Stearo-Ampoule
225-650		B-S-AMP-10-6		10^6 CFU	
235-510	100	B-S-MAMP-10-5	5 x 25 mm	10^5 CFU	Mini Stearo-Ampoule
235-610		B-S-MAMP-10-6		10^6 CFU	

Performance Characteristics

The Stearo-ampoules are manufactured according to the standard EN ISO 11138-1 + -3 as well as the USP and EP guidelines. Population and D-value are tested with each production batch according to the standard and documented in the corresponding certificate.

Benefits

- Applicable in both 121°C and 134°C processes.
- Manufactured in Germany.
- Stearo ampoules are manufactured according to the current EN ISO standards as well as the European and American Pharmacopoeia.
- Each batch contains a certificate showing the analysis data of the population and the D-value under precisely defined sterilization conditions.
- Guaranteed shelf life of 12 months after production.
- Permanent quality monitoring of each batch until the expiry date.
- Mini ampoules available to perform sterility testing within small sterile packages (e.g. ophthalmic lenses).
- Rapid incubation by optimizing the nutrient solution with pH indicator. Suitable GKE incubator available from Mesa Germany.
- No negative control necessary.
- Consistent quality according to quality management system EN ISO 13485.

